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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,437	12/21/2000	Gregory S. Hamilton	23758	7495

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,437

Applicant(s)

HAMILTON, GREGORY S.

Examiner

Laura L. Stockton, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). -In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 67 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 63-65 is/are rejected.
- 7) ☒ Claim(s) 4, 5 and 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-5 and 63-68 are pending in the application.

Response to Amendment

In the Response to the Statement of Non-responsiveness, Applicant argues that there is no requirement in Rule 121 to change an identifier of a withdrawn claim from “previously presented” (as identified in the Amendment filed April 23, 2004) to “withdrawn” as stated in the Non-responsive letter mailed July 2, 2004, although Applicant has made the change.

In response, Rule 1.121 does require this change. The following is taken from Rule 1.121. See especially the last sentence in (c)(2).

- (c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (*e.g.*, additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

- (1) *Claim listing*. All of the claims presented in a claim listing shall be

presented in ascending numerical order. Consecutive claims having the same status of "canceled" or "not entered" may be aggregated into one statement (*e.g.*, Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

- (2) *When claim text with markings is required*. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of "currently amended," and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of "currently amended," or "withdrawn" if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as "withdrawn—currently amended."

Election/Restrictions

Claims 67 and 68 are withdrawn as pertaining to a non-elected invention. See the Restriction Requirement dated July 26, 2001 {Paper No. 4} and Applicant's election dated August 22, 2001 {Paper No. 5}.

Rejections made in the previous Office Action which do not appear below have been overcome. Therefore, arguments pertaining to these rejections will not be addressed.

Claim Rejections – 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C.

112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and

distinctly claim the subject matter which applicant regards as the invention.

The number of provisos added to claim 1 makes claim 1 indefinite. 35 USC § 112, second paragraph states that the claims should particularly point out and distinctly claim the subject matter which the applicant regards as his invention. In Applicant adding a tenth proviso, claim 1 is directed more toward the subject matter that is not Applicant's invention instead of the subject matter which the Applicant regards as his invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3 and 65 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,503,244 .

The GB reference disclose, for instance, Example 1(A) in water (page 6) and Example 6 in ethanol on page 12 that are embraced by the instant claims.

Response to Arguments concerning 102(b) rejections

Applicant's arguments filed April 23, 2004 have been fully considered. Applicant argues that the issue is not whether water is a pharmaceutically acceptable carrier but what GB 1,503,244 describes. Applicant argues that GB 1,503,244 describes that the compound of Example 1(A) is washed with water and recrystallized from acetone-water.

In response, GB 1,503,244 describe a pharmaceutical composition of Example 1(A) in water when Example 1(A) was washed with water. The fact that Example 1(A) was later recrystallized from acetone-water does not negate the fact that Example 1(A) was washed with water, a

known pharmaceutically acceptable carrier. Also see page 41, line 17 and page 42, line 22 of the instant specification where it lists "water" as a pharmaceutically acceptable carrier.

Additionally, GB 1,503,244 teaches carriers (page 17, lines 39-44), such as alcohols, kaolin, talc, etc., that are known in the pharmaceutical art as pharmaceutically acceptable carriers. See, for example, Jamieson et al., column 3, lines 24-68 and column 4, lines 1-16. Further, Example 6 on page 12 is in ethanol (e.g., a pharmaceutically acceptable carrier). See, for example, Bender {U.S. Pat. 4,186,205}, column 4, lines 6-14 also for known pharmaceutically acceptable carriers. The rejection is deemed proper and therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art

are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakabayashi et al. {JP 52-083686}, GB 1,503,244 and Jamieson et al. {U.S. Pat. 4,230,709}, each taken alone or in combination with each other when similar utilities are asserted. An English translation of JP 52-083686 has been supplied with a previous Office Action and will be referred to hereinafter.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims hydantoin products. Wakabayashi et al. {page 3, Table 1 on pages 9-13, and page 17}, GB 1,503,244 {page 2, Formula I; Table 1 pages 8-11; page 17, lines 39-44; and Example 1(A), page 6 and Example 6, page 12} and Jamieson et al. {column 1, Formula I; column 3, lines 24-68; column 4, lines 1-16; and Examples 6 and 8 in column 5} each teach hydantoin products which are either structurally the same as (see above 102 rejection) or structurally similar to the instant claimed products.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between some of the products in the prior art and the products instantly claimed is that the prior art generically describes the instantly claimed products.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The indiscriminate selection of “some” among “many” is *prima facie* obvious, *In re Lemin*, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating asthma).

One skilled in the art would thus be motivated to prepare compounds embraced by the reference genera to arrive at the instant claimed products with the expectation of obtaining compounds which would be useful in treating, for example, asthma. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant invention would have been obvious to one skilled in the art.

Response to Arguments concerning 103 rejections

Applicant's arguments filed April 23, 2004 have been fully considered. Applicant argues that the combination of teachings is improper since the teachings in the cited prior art are disparate. In response, both Wakabayshi et al. (page 3, second paragraph) and GB 1,503,244 (page 1, second paragraph) each teach that their hydantoin products have herbicidal activity. Therefore, it is proper to combine the teachings to these two references.

Applicant argues that even if GB 1,503,244 were to teach an isomer of any compound of claim 3 or 65, that alone would not be enough to render that claim *prima facie* obvious since there is no reason to add the cited compound to a pharmaceutically acceptable carrier to form a pharmaceutical composition. Applicant argues that Wakabayshi et al. would not render the instant claims obvious for the same reason as stated for GB 1,503,244. In response, in order to meet the limitations of instant claims 3 and 65, the prior art reference has to have: 1) a compound of the formula; and 2) a pharmaceutically acceptable carrier.

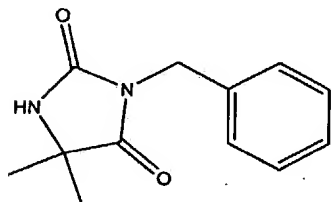
GB 1,503,244 teaches: 1) a compound embraced by Applicant's formula and 2) carriers that are known in the pharmaceutical art to be useful as pharmaceutically acceptable carriers. See specifically Example 6 in ethanol on page 12 of GB 1,503,244. Wakabayashi et al. teach: 1) a compound embraced by Applicant's formula and 2) carriers that are known in the pharmaceutical art to be useful as pharmaceutically acceptable carriers. See page 17 where it states that, "the compounds having the compound numbers shown in Table 3 below in a water-dispersible-powder form were diluted in water." See also Compound 2 in Table 1 on page 9, Compound 3 in Table 1 on page 9, etc.

Applicant argues that there must be some motivation or suggestion to make the claimed invention and that a *prima facie* case has not been established even if a genus embraces a species. Applicant argues that the genus in Jamieron et al. is too big and the cited genus fails to anticipate any particular species or subgenus. In response, it is disagreed that the scope Jamieron et al. is too broad. The scope of instant claim 3 is very large. Note specifically the definition of the R variable which is defined

as an alicyclic or aromatic ring that can be a monocyclic ring, a bicyclic ring or a tricyclic ring, and in which the alicyclic or aromatic ring can be carbocyclic ring or a heterocyclic ring. Additionally, the test for obviousness is not predicated on whether or not a species in the prior art anticipate the claims. The only requirement is that the prior art provide motivation to prepare the claimed products, in which Jamieron et al. do.

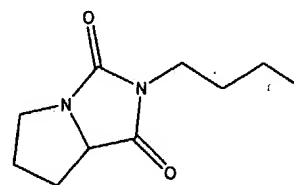
Applicant argues Example 6 and Example 8 (both shown below) in Jamieron et al., which were specifically noted by the Examiner, and each of these compounds differences from the products instant claimed. Applicant further argues that Jamieron et al. teach that compounds which R³ is C₁₋₄ alkyl such a n-butyl are preferred.

Example 6



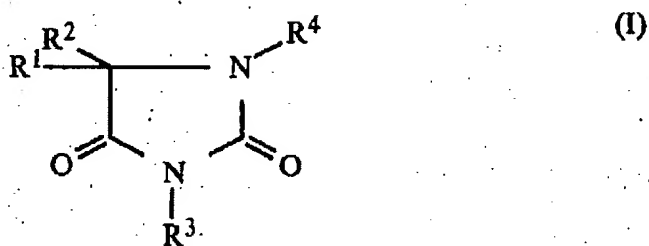
3-Benzyl-5,5-dimethyl-2,4-imidazolidine-dione

Example 8



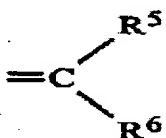
2-n-Butyl-tetrahydro-1H-pyrrolo[1,2-c]imidazole-1,3-(2H)-dione

All of Applicant's arguments have been considered but have not been found persuasive. Formula (I) of Jamieron et al. has been reproduced below.



wherein

**R¹ is C₁₋₄ alkyl, R² is hydrogen or C₁₋₄ alkyl;
or R¹ and R² taken together either represent a C₄₋₆
alkylene group or a group of formula:**



where

**R⁵ and R⁶ independently represent hydrogen or C₁₋₄
alkyl;**

R³ is C₁₋₆ alkyl or benzyl;

R⁴ is hydrogen or C₁₋₆ alkyl;

provided that R² and R⁴ cannot both be hydrogen;

**or R¹ and R⁴ taken together represent a C₂₋₄ alkylene
group;**

**associated with a pharmaceutically-acceptable carrier
therefor.**

Example 6 (column 5) was highlighted to show that Jamieron et al. would direct one skilled in the art to prepare compounds wherein a “benzyl” group is present in the R^3 variable position in Formula (I). Example 8 (column 5) was highlighted to show that Jamieron et al. would direct one skilled in the art to prepare compounds in which: (1) the R^1 and R^4 variables taken together represent a C_3 alkylene group; and (2) an C_{1-6} alkyl group is present in the R^3 variable position in Formula (I). If not for proviso #1 {wherein when R is hydrogen, then D is C_5 - C_7 alkyl} in instant claim 1 (page 3, line of the Amendment filed July 8, 2004), Example 8 would have anticipated the instant claims.

At the very least, the butyl group, {a C_4 alkyl represented by the R^3 variable} in Example 8 of Jamieron et al. is a homolog of the instant claimed compounds in claim 1 (e.g., butyl in Jamieron et al. versus pentyl, which is instantly claimed). A comparison is made of the products disclosed in Jamieron et al. and the fourth compound listed in instant claim 2 (instant claim 2 is a compound claim). Example 8 in Jamieron et al. is 2-n-**butyl**-tetrahydro-1H-pyrrolo[1,2-c]imidazole-1,3-

(2H)-dione whereas the fourth compound listed in instant claim 2 is 2-hexyl-tetrahydro-1H-pyrrolo[1,2-c]imidazole-1,3-(2H)-dione {or 2-hexyl-2,5,6,7,7a-pentahydro-2-azapyrrolizine-1,3-dione}. The only difference in the two products is a C₄ alkyl versus a C₆ alkyl (e.g., butyl in Jamieson et al. versus hexyl instantly claimed), and butyl and hexyl are both in the lower alkyl homolog series.

To those skilled in chemical art, one homologue is not such an advance over adjacent member of series as requires invention because chemists knowing properties of one member of series would in general know what to expect in adjacent members. *In re Henze*, 85 USPQ 261 (1950). However, the Jamieson et al. teach a C₁₋₆ alkyl at the R³ variable position (Formula I in column 1) to have the desired activity.

Further, Jamieson et al. not only prepares Example 8, Jamieson et al. teach pharmaceutical formulations (column 3, lines 55-68; and column 4, lines 1-16) which are useful in treating asthma. Additionally, it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire

disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. *In re Boe*, 148 USPQ 507, 510 (CCPA 1966).

Therefore, the prior art references do suggest the instant claimed invention and would motivate one skilled in the art to prepare additional products embraced by the prior art with the expectation of obtaining products that would have, for example, herbicidal activity or would be useful in treating asthma. For all the reasons given above, the rejection is proper and is maintained.

Allowable Subject Matter

Claims 4, 5 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

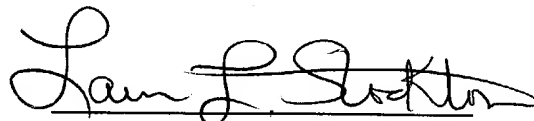
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

September 27, 2004